JC18 Rec'd PCT/PTO 14 JUL 2005

Docket No.: 1373 (6-11407-1177)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE 242501

Applicants:	Ronald W. Wood	į
U. S. Serial No:	To be assigned)
Filed:	Herewith)
PCT International Application No:	PCT/US2004/000961)
Filed:	15 January 2004)
For:	QUATERNARY ANTIMUSCARINIC COMPOUNDS FOR THE TREATMENT OF BLADDER DISEASES)

INFORMATION DISCLOSURE STATEMENT

Mail Stop: PCT

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Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. 1.56, 1.97, and 1.98, applicants hereby bring to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO-1449 form. Published art included in the International Search Report (copy enclosed) of the corresponding PCT application, is cited for consideration and listed on the enclosed PTO-1449 form as reference numbers 3-5, 15, and 26. These references are relevant for the reasons given in the search report.

Because copies of the references indicated in the International Search Report should have been transferred by the International Searching Authority ("ISA"), duplicate copies are <u>not</u> enclosed herewith. Should the U.S. Patent and Trademark Office ("PTO") require a copies of the references from applicants (i.e., the ISA has not provided them), the PTO should contact the undersigned representative directly.

Pursuant to 37 C.F.R. § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

Respectfully submitted,

Date:

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R862724.1

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10/542501 PTO/SB/08A (10-01)

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Complete of Khowl 14 Substitute for form 1449A/PTO To Be Assigned **Application Number** INFORMATION DISCLOSURE Herewith Filing Date STATEMENT BY APPLICANT Ronald W. Wood First Named Inventor (use as many sheets as necessary) To Be Assigned Art Unit To Be Assigned Examiner Name of Attorney Docket Number 176/61373 (6-11407-1177)* Sheet

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				U.S. PATENT DOCU	MENT	S		T			
Examiner Initials	Cite No. ¹	U.S. Patent Document Number - Kind Code ² (if known)		Publication Date MM-DD-YYYY		Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	1	US-5,001,160	03.	/19/1991		McPherson e	t al.				
****	2	US-5,552,407	09	/03/1996		Wood et al.					
	3	US-5,610,163	03.	/11/1997		Banholzer et	al.				
	4	US-5,654,314	08.	/05/1997		Banholzer et	al.				
	5	US-5,770,738	06.	/23/1998		Banholzer et	al.				
	6	US-5,821,249	10.	/13/1998		Wood et al.					
	7	US-6,482,837	11.	/19/2002		Wood					
	8	US-6,573,282	06	/03/2003		Yaksh et al.					
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	9	"Anticholinergic Therapy: The State of the Art. Proceedings of a Symposium Held in Stratford-Upon Avon 8-9 September 1986," Higgenbottam et al., eds., <i>Postgrad. Med. J.</i> 63(Suppl 1):1-86 and Poster Abstracts and Discussion 63(Suppl 1):1A-31A (1987)									
	10	1	Autret et al., "Plasma Levels of Oxybutynine Chloride in Children," Eur. J. Clin. Pharmacol. 46:83-85 (1994)								
	Barbalias, G.A., "Interstitial Cystitis: Bladder Training with Intravesical Oxybutynin," Urol. 163:1818-1822 (2000)						Oxybutynin," J.				

Examiner	Date	
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Substitute for form 1449B/PTO				Complete if A 10 1 542 5 0 1		
INFORMATION DISCLOSURE				Application Number	To Be Assigned	
		Filing Date	Herewith			
SIA	STATEMENT BY APPLICANT		First Named Inventor	Ronald W. Wood		
	(use as many sheets	as necesso	ary)	Group Art Unit	To Be Assigned	
			Examiner Name	To Be Assigned		
Sheet	2	of	4	Attorney Docket Number	176/61373 (6-11407-1177)	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	12	Brendler et al., "Topical Oxybutynin Chloride For Relaxation of Dysfunctional Bladders," J. Urol. 141:1350-1352 (1989)	
	13	Brown et al., "Proceedings of the National Institute of Diabetes and Digestive and Kidney Diseases International Symposium on Epidemiologic Issues in Urinary Incontinence in Women," Am. J. Obstet. Gynecol. 188:S77-S88 (2003)	
	14	Chen et al., "Pulmonary Effects of the Cocaine Pyrolysis Product, Methylecgonidine, in Guinea Pigs," <i>Life Sciences</i> 56(1):7-12 (1995)	-
	15	Davilla, G.W., "Advances in Anticholinergic Therapy Delivery Systems," <i>Urology Times</i> , pp. 1-2 (June 2002)	
	16	Disse et al., "Ba 679 BR, A Novel Long-Acting Anticholinergic Bronchodilator," <i>Life Sciences</i> 52:537-544 (1993)	
	17	Disse et al., "Tiotropium (Spiriva TM): Mechanistical Considerations and Clinical Profile in Obstructive Lung Disease," <i>Life Sciences</i> 64(6/7):457-464 (1999)	
	18	Eichel et al., "Assessment of Murine Bladder Permeability with Fluorescein: Validation With Cyclophosphamide and Protemine," <i>Urology</i> 58(1):113-118 (2001)	
	19	El-Fawal et al., "Airway Smooth Muscle Relaxant Effects of the Cocaine Pyrolysis Product, Methylecgonidine," J. Pharm. Exp. Ther. 272(3):991-996 (1995)	
	20	Gearien, J.E., "Cholinergics, Acetylcholinesterases, and Antispasmodics," Foye, W.O., eds., <i>Principles of Medicinal Chemistry</i> , Lean and Febiger, Philadelphia, PA, Chapter 15, pp. 323-341 (1989)	
	21	Franstz et al., "Implementing an Incontinence Management Protocol in Long-Term Care," J. Gerontological Nursing 29(8):46-53 (2003)	
	22	Heller et al., "Muscarinic Receptor Agonists and Antagonists," Goodman and Gilman, The Pharmacological Basis of Therapeutics, 10 th Edition, Hardman et al., eds., McGraw-Hill, Chapter 7, pp. 155-173 (2000)	
	23	Green et al., "Urinary Incontinence in Subacute Care – A Retrospective Analysis of Clincal Outcomes and Costs," <i>MJA</i> 178:550-553 (2003)	
	24	Greenfield et al., "The Use of Intravesical Oxybutynin Chloride in Children with Neurogenic Bladder," <i>J. Urol.</i> 146:532-534 (1991)	

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INFORMATION DISCLOSURE				Application Number	To Be Assigned	
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SIAI	STATEMENT BY APPLICANT		First Named Inventor	Ronald W. Wood		
	(use as many sheets as necessary)			Group Art Unit	To Be Assigned	
		Examiner Name	To Be Assigned			
Sheet	3	of	4	Attorney Docket Number	176/61373 (6-11407-1177)	

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T ²
Initials*	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	15
	25	Gross, H.J., "Ipratropium Bromide," New. Eng. J. Med. 319:486-494 (1988)	
	26	Hay-Smith et al., "Anticholinergic Drugs Versus Placebo for Overactive Bladder Syndrome in Adults," <i>Cochrane Database Syst. Rev.</i> 3:CD003781 (2002) (Abstract)	
	27	Hogan, D.B., "Revisiting the O Complex: Urinary Incontinence, Delirium and Polypharmacy in Elderly Patients," <i>Can. Med. Assoc. J.</i> 157(8):1071-1077 (1997)	
	28	Hu et al., "Estimated Economic Costs of Overactive Bladder in the United States," Urology 61(6):1123-1128 (2003)	
	29	Krishnan, K.R., "A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multicenter Study of Intravesical Oxybutynin," <i>Neurourol. And Urodyn.</i> 15:307-308 (1996) (Abstract #32)	
	30	Langtry et al., "Terodiline. A Review of its Pharmacological Properties, and Therapeutic Use in the Treatment of Urinary Incontinence," <i>Drugs</i> 40(5):748-761 (1990)	
	31	Madersbacher et al., "Control of Detrusor Hyperreflexia by the Intravesical Instillation of Oxybutynine Hydrochloride," <i>Paraplegia</i> 29:84-90 (1991)	
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	33	Norman et al., "Tiotropium Bromide, Treatment of COPD Bronchodilator Muscarinic Antagonist," <i>Drugs of the Future</i> 25(7):693-699 (2000)	
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	35	Pietzko et al., "Influences of Trospium Chloride and Oxybutynin on Quantitative EEG in Healthy Volunteers," Eur. J. Clin. Pharmacol. 47:337-343 (1994)	
	36	Scheidweiler et al., "Pharmacokinetics and Pharmacodynamics of Methylecgonidine, a Crack Cocaine Pyrolyzate," <i>J. Pharm. Exp. Ther.</i> 307(3):1179-1187 (2003)	
,	37	Sessions et al., "Continuous Bladder Infusion Methods for Voiding Function in the Ambulatory Mouse," <i>Urology</i> 60(4):707-713 (2002)	

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	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS						
Examiner nitials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²				
	38	Shih et al., "Labor Costs Associated with Incontinence in Long-Term Care Facilities," Urology 62(3):442-446 (2003)					
	39	Takahashi et al., "Effect of Ba 679 BR, A Novel Long-Acting Anticholinergic Agent, On Cholinergic Neurotransmission in Guinea Pigs and Human Airways," Am. J. Resp. Crit. Care Med. 150:1640-1645 (1994)					
	40	Thuroff et al., "Randomized, Double-Blind, Multicenter Trial on Treatment of Frequency, Urgency and Incontinence Related to Detrusor Hyperactivity: Oxybutynin Versus Propantheline Versus Placebo," <i>J. Urol.</i> 145:813-817 (1991)					
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	44	Witek, T.J. Jr., "Anticholinergic Bronchodilators," Respiratory Clinica of North America 5:521-536 (1999)					
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	46	Wood et al., "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity," <i>Pharmacology, Biochemistry & Behavior</i> 55(2):237-248 (1996)					
	47	Wood et al., "Uroflow in Murine Urethritis," Research Insights into Interstitial Cystitis: A Basic and Clinical Science Symposium, Alexandria, VA, October 30-November 1, 2003; co-presented by the National Institute of Diabetes and Digestive and Kidney Diseases and the Interstitial Cystitis Association (Abstract and Poster Presentation) (2 pp.)					

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